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801 Pennsylvania Avenue, N.W.
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| EXAMINER |
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EREZO, DARWIN P

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3731

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/963,676
Filing Date: September 27, 2001
Appellant(s): CHIN ET AL.

MAILED
MAR 28 2007
Group 3700

John A. Bauer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/17/2006 appealing from the Office action mailed 02/06/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|-----------|-------------|--------|
| 5,425,376 | BANYS ET AL | 6-1995 |
| 6,574,497 | PACETTI | 6-2003 |

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4,588,399

NEBERGALL ET AL

5-1986

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 27, 28, 31, 35-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,425,376 to Banys et al. and in view of US 6,574,497 to Pacetti.

Banys teaches a method for determining a length of exposure of a tissue cutting device from a catheter/cannula by observing the tissue cutting device which is entirely made of radiopaque (col. 6, line 9), then deploying said cutting device to the tissue. The length of the exposure of the cutting device is related to the distance of which the cannula is withdrawn (col. 6, lines 3-10). Though Banys teaches the cutting device being radiopaque, he fails to teach the radiopaque material arranged as a plurality of

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radiopaque indicia at measurable intervals. However, as seen in Fig. 3 of Pacetti, it is known in the art to provide a cutting device (needle, see abstract) with a plurality of radiopaque indicia at measurable intervals (for example: **60, 62**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Banys to include a plurality of spaced radiopaque indicia because having said plurality of spaced radiopaque indicia would allow the practitioner to monitor the distal and proximal portion of the biopsy needle, which would provide better positional accuracy than a single radiopaque indicia (the needle). Also, the distal or proximal radiopaque indicia is fully capable of being used as a reference point, as in a leading indicia or trailing indicia. The above combination of Banys/Pacetti also teaches the arrangement of the recited device claims, as the structure is also recited in the method steps. Pacetti also discloses having more than two radiopaque indicia, as seen in Fig. 10.

4. Claims 29, 32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banys et al. in view Pacetti, and in further view of US 4,588,399 to Nebergall et al.

Banys teaches using a radiopaque biopsy needle to determine the location of a cutting device from a cannula but does not specifically recite the cannula having a radiopaque material. However, it would be obvious to one of ordinary skill in the art to use a cannula having a radiopaque tip, such as the one taught by Nebergall, because in order to determine the location of the cutting device relative to the cannula, it would be necessary to use the cannula as a reference point. Since Banys teaches using

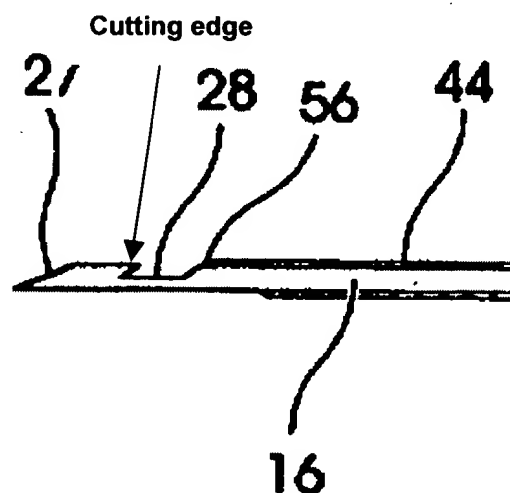
fluoroscopy to monitor the needle, it would be obvious to provide a reference point that is also usable under fluoroscopy, such as a cannula with a radiopaque tip.

(10) Response to Argument

Response to arguments concerning the Banys reference:

The appellant argued that Banys allegedly fails to disclose a catheter having a tissue cutting device that is disposed in a catheter lumen, the cutting device disposed for extension out of an opening of the catheter lumen.

However, this is not persuasive because Banys discloses a tubular cannula structure **14** that is being viewed by the examiner as a catheter, which is merely a tubular medical device. Banys further discloses a needle **16** that is disposed within the lumen of the cannula structure **14**, as shown in Fig. 1. The needle is disclosed as comprising a lateral opening **28** and a cutting edge which shown in the attached figure below.



The lateral opening **28** receives a tissue portion when hub flange **48** is pulled upward, as shown in Fig. 5. Once the hub flange **48** is released, the tissue located within the lateral opening **28** is cut by the cutting edge shown in the figure above and the distal end **56** of the cannula **14**. This type of cutting means is similar in concept to a sliding cigar cutter, where two cutting edges are provided for cutting. Therefore, since both the distal end **56** of the cannula and the cutting edge of the needle are viewed as cutting edges, Banys clearly discloses at least one cutting edge disposed within the lumen of the cannula **14**, as shown in Fig. 4.

With regards to the arguments that Banys does not disclose a device in which the "tissue cutting device has a cutting member disposed for extension out of the lumen, the appellant is directed towards Fig. 5, which shows the cutting edge of the needle to be disposed outside of the lumen of the cannula.

The appellant further argued that even if the combined structure of the cutting edge and the distal end **56** of the cannula are viewed to be the cutting device, there is still no distance between the sharp leading edge of the cannula and the edge of opening **28** of the needle because the leading edge of the cannula forms part of the cutting device (page 13, last paragraph of the Appeal Brief). However, this is not persuasive because the cutting edge of the needle shown above is still fully capable of cutting tissue on its own and is capable of being disposed outside the lumen of the cannula. Thus, the cutting edge of the needle is viewed as the tissue cutting device that is exposed from the distal portion of the lumen of the cannula

The appellant also argued that Bany's fails to disclose a needle knife (page 15, last paragraph of the Appeal Brief). This is not found persuasive as Bany's clearly shows a needle **16** having a cutting edge shown in the figure above. Thus, the needle **16** is viewed as a needle knife.

Response to arguments regarding the Pacetti reference:

The appellant provided the same arguments as cited in the arguments for the Bany's reference.

Response to argument regarding the Nebergall reference:

The appellant provided the same arguments as cited in the arguments for the Bany's reference, and the following: the appellant also argued that there is no motivation to combine the teachings of Nebergall with Bany's and Pacetti. The appellant stated that one skilled in the art would not be motivated to determine the area of the needle that is exposed between the lateral opening and the distal end of the cannula. However, this is not persuasive because the operation of the device of Bany's requires that the lateral opening **28** of the needle be exposed from the distal end of the cannula in order to receive a tissue to be sampled for biopsy. Therefore, one of ordinary skill in the art would have been motivated to provide radiopaque indicia on the cannula because it allows the cannula to be used as a reference point in order to determine the distance between the lateral opening of the needle and the distal end of the cannula. This would allow a practitioner to visually verify that the lateral opening of the needle is spaced away from the distal end of the cannula.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

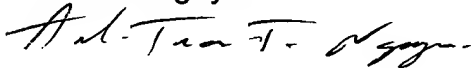
Respectfully submitted,

Darwin Erez



Conferees:

Anhtuan Nguyen



Janet Baxter, TQAS